VAMHCS RESEARCH SERVICE BULLETIN

April 1, 2011

- **Investigators must be compliant with revised VHA handbook 1200.05 by 3/31/2011.**
- **Reminder of new requirement for master lists of all individuals who sign research consent forms.**

Please refer to VHA Handbook 1200.05, "Requirements for the Protection of Human Subjects in Research" (issued on 10/15/2010) for details on compliance with this handbook. You may also refer to Research Service Hot Topic "New VHA Handbook Expands Investigator Responsibilities" (Vol. 4, No. 4 issued 12/13/2010) for a summary of some main points that affect investigator conduct of VA research.

In particular, please remember the ***new requirement to maintain a master list of all individuals who sign research consent forms***. [1200.05 Item 9u, page 26]

- This must be done whether or not the IRB has granted a waiver of documentation of informed consent.
- Do not add a participant's name to the master list until after:
  - Informed consent has been obtained from the individual, and
  - When appropriate, informed consent has been documented using the IRB-approved informed consent form.
- The IRB may waive the requirement for the investigator to maintain the master list for a given study if both of the following are met:
  - There is a waiver of documentation of informed consent, and
  - The IRB determines that including the participants on such a master list poses a potential risk to the participants from a breach of confidentiality.
- Secure the master list in compliance with all VA confidentiality and information security requirements in your study files.

If you have further questions, please contact: Jessica Mendoza at Jessica.mendoza@va.gov, 410-605-7000 x6512.